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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,927	04/10/2002	Jurgen Stoltefuss	LE A 33 783	8267

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EXAMINER

BERNHARDT, EMILY B

ART UNIT

PAPER NUMBER

1624

8

DATE MAILED: 05/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
10/018,927

Applicant(s)  
STOLTEFUSS ET AL.

Examiner  
Emily Bernhardt

Art Unit  
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 3/17/03 (preliminary amendment).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10-15, 19, and 20 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-15, 19, and 20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s): \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s): 21/01 & 6) ☐ Other:

Art Unit: 1624

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Should the case ever pass to issue the printer would not accept the abstract appearing on the cover page of applicants' PCT publication as part of the instant disclosure.

The disclosure is objected to because of the following informalities: In the tables on pp.30 and 32 for examples 26 and 50, a thiazoline ring is depicted rather than thiazole described as part of the genus. Is this correct? Note the molecular weight given. See *In re Nathan* 140 USPQ 601.

Claims 1,4-6,10-15,19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. In the R6 definition on p.4 in claim 1, the "and" before "aryl" should be removed and replaced by a comma since "aryl" is apparently not the last substituent for alkyl but the "aromatic heterocycles" are. Otherwise, it could be construed that said rings are alternate choices for R6, which is not applicants' intent from seeing the dependent claims.

Art Unit: 1624

2. Nature of substituents for the NR5R6 rings recited on p.5 of claim 1 is not given in the claim or in the specification as far as the examiner can determine.

Claims 1,4-6, 10-15,19 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Scope of hetero aromatic rings recited in the main claims in the R6 choices is not adequately enabled as the scope reads on 5- to 7-membered aromatics having up to 3 heteroatoms (S,N,O) in any array yet compounds made and presumably tested represent the scope of claim 2. There is thus no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note In re Surrey 151 USPQ 724 regarding sufficiency of disclosure for a Markush group. Also see MPEP 2164.03 for enablement requirements in cases directed to structure-sensitive arts such as the pharmaceutical art. Also note the criteria for enablement as set out in In re Wands cited in MPEP 2164.01(a), August 2000 edition. Thus

Art Unit: 1624

given the breadth of the claims, the level of unpredictability in the art and the lack of direction (i.e. working examples) provided as to what other 5-7 membered **aromatic heterocycle** rings might work, this rejection is being applied.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curran (DE'436 or J.Med. Chem.) in view of March. Curran teaches very similar compounds for use as hypotensives. See eg.4 in the DE publication provided by applicants and the same compound (no.18) in a related article provided by the examiner. Closest instant compound which requires 2 methyl groups on the carboxamide nitrogen are obvious variants of unsubstituted derivative taught by Curran since compounds that differ only in having H vs alkyl on a nitrogen are not deemed patentably distinct absent evidence of superior, unexpected results. Note In re Doebel 174 USPQ 158; Ex parte Weston 121 USPQ 428. Claim 5 which recites a process of making carboxamide derivatives is also obvious given the well known

Art Unit: 1624

teaching in the process art such as March (pertinent pages provided ) which teaches the instant two-step reaction of route (B) as a well known, versatile way for ultimately preparing carboxamides. Thus it would have been obvious to one skilled in the art at the time the invention was made to expect instant alkyl (eg.methyl) substituted derivatives of Curran's compound to also be useful as blood pressure lowering agents in view of the close structural similarity outlined above and their preparation within the ordinary skill of the art.

It is stated in the specification (on p.7) that the N-monomethyl carboxamide is described in the DE publication applied above. This compound has been excluded by applicants' proviso. The examiner cannot find this species in the DE reference nor in US Curran, also cited by applicants. In fact the US disclosure is much narrower and not relevant to the instant claims. The excluded species was not picked up by a CAS structure search. Applicants' comment(s) are invited.

The IDS filed 6/19/02 has been considered . The examiner is not fluent in German but the references appear to be only background information directed to applicants' disclosed use.

Art Unit: 1624

**Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.**

**A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.**



**EMILY BERNHARDT**

**PRIMARY EXAMINER**

**GROUP 1600**